OVER 30 YEARS OF EXPERIENCE IN MEDICAL TECHNOLOGY

30 YEARS

Stelia Stem
Surgical Technique

swiss design
swiss made
swiss quality

stemcup

Medical products in motion

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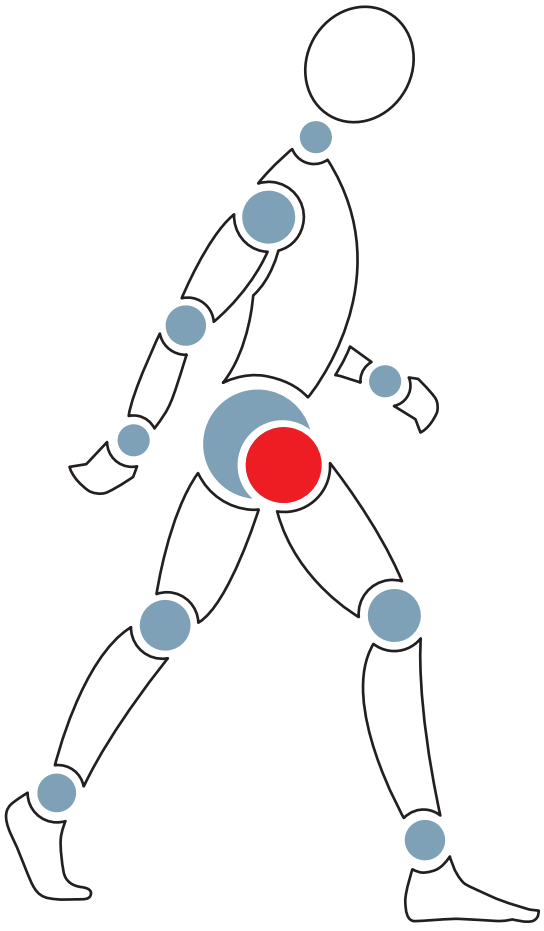
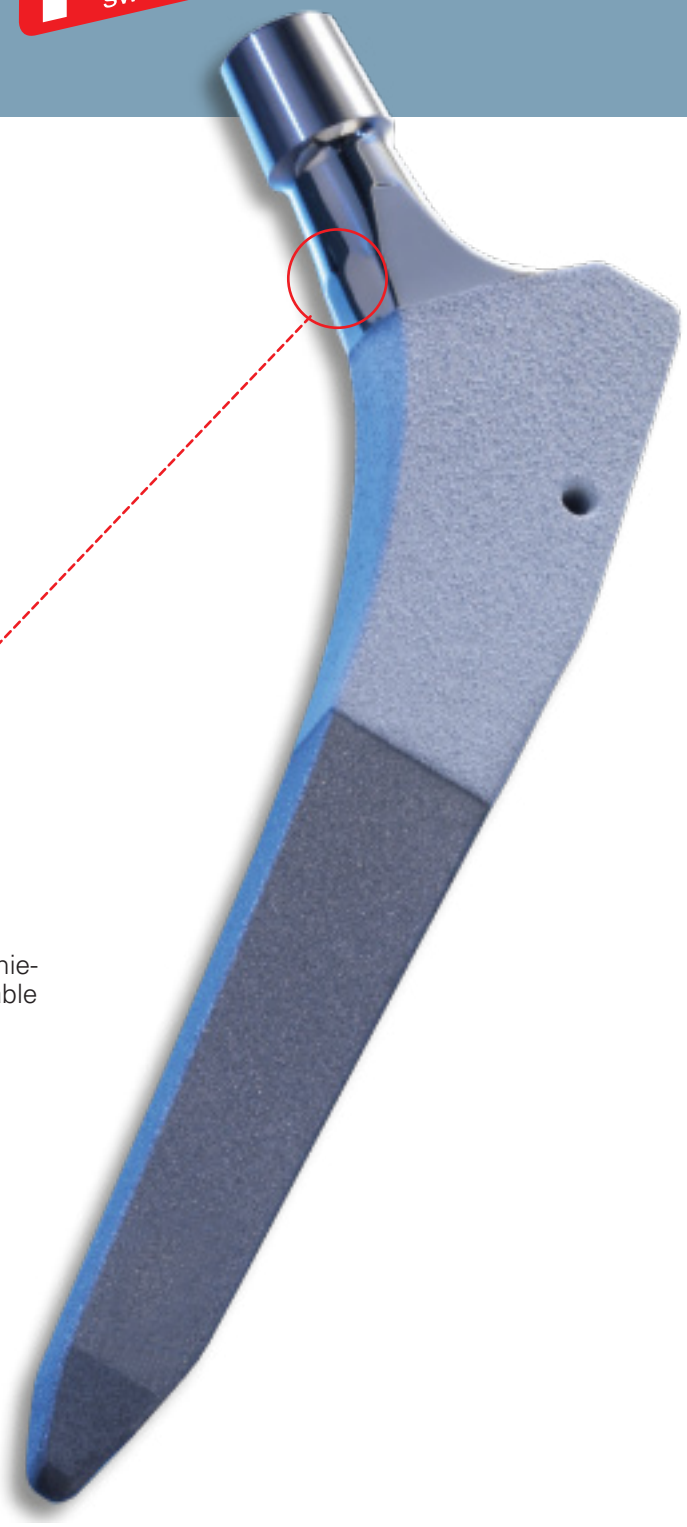


Nota Bene

The technique description herein is made available to the health-care professional to illustrate the authors' suggested treatment for the uncomplicated procedure. In the final analysis, the preferred treatment is that which addresses the needs of the patient.

1. System description

swiss design
swiss made
swiss quality



1.1 Prosthesisdesign

- Standard and lateralized design
- Rectangular, double conical straight stem design
- Material: forge alloy Ti6Al7Nb, ISO 5832-11
- Grid blasted surface with a roughness Ra 4 - 6 µm
- Coating: Porous Ti/HA-VPS coating

Stelia stem standard

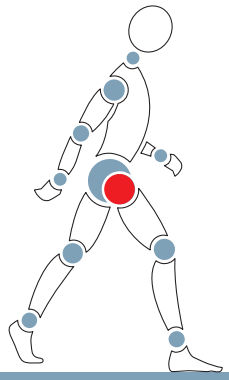
- 12 sizes (01-10)
- CCD-Angle of 131°

Stelia stem lateralized

- 9 sizes (1-9)
- CCD-Angle of 127°

Polished is brilliant in use

The neck of the prosthesis is polished in order to achieve an even higher durability of the already highly durable titanium-forged alloy.



2. Indications / Contraindications / E-IFU

A prosthesis should be considered only after all other surgical methods of treatment and/or conservative measures have been carefully weighed against each other and none has been judged to be more appropriate. Even a most successfully implanted artificial joint is inferior to a normal, sound joint. On the other hand, an artificial joint can be a highly beneficial substitute for a severely deformed and diseased joint, and is consequently a blessing for the suffering patient, because it eliminates pain and is conducive to the restoration of good mobility and weight-bearing capacity. Every artificial joint is subject to wear, which still remains a major problem awaiting solution. An initially stable prosthesis may become loose in the course of time. Wear and loosening are two major causes that may render revision surgery necessary. The following criteria should be taken into account to ensure optimum durability of the Stelia stem:

2.1 Indications

It follows, from the above statements, that a prosthesis is indicated in cases where some of the following five basic conditions are fulfilled:

- noninflammatory degenerative joint disease (NIDJD) for example: osteoarthritis (arthrosis primary-, secondary- ,dysplasia-coxarthrose).
- inflammatory joint disease (IJD) for example: rheumathoide arthritis, post-traumatic arthritis condition resulting from previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement.
- Condition resulting from previous surgery, e.g. osteosynthesis, joint reconstruction, arthrodesis, hemiarthroplasty or total hip replacement.
- fracture or avascular necrosis of the femoral head

The surgeon should inform the patient of the risks associated with the implantation of a prosthesis, and the patient must consent to the operation, and if necessary , sign the relevant declaration.

The following circumstances require special attention, as the can cause premature failure
of the implants, like stem fractures, loosing, or increased abrasions.

- patient's overweight
- extreme loading expected as a result of work and sport
- epilepsy or other factors favouring repeated accidents with increased risk of fracture
- osteoporosis or osteomalacia
- past history and ongoing risk of infectious diseases with potential arthropathic manifestations
- severe deformation of the affected joint, which may render fixation of the implant more difficult
- weakening of the supporting structures due to tumours
- alcoholism or other addictions
- the taking of highly dosed cortisone or cytostatic drugs
- patient's mental inability to understand and follow the attending surgeon's instructions
- patients whose skeletons are not completely formed or are still growing.

A risk/benefit analysis is the responsibility of the treating physician. Note however that STEMCUP does not accept any liability in any case for such uses.

2. Indications / Contraindications / E-IFU

2.2 Contraindicatons

The following conditions are generally accepted as contraindications to the implantation of a joint prosthesis:

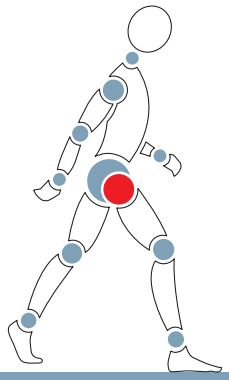
- acute or chronic infection (local or systemic)
- severe muscular, neurological or vascular disease threatening the extremity concerned
- loss of bone structure or poor quality of bone, precluding proper anchorage of the implant
- any concomitant disease which may compromise the function of the implant
- possible patient allergy to the material(s) used in the implant or prosthesis

2.3 E-IFU

The E-IFU (Instruction for Use) is available online. On the product labels there will be the link to www.stemcup.com. On this website the electronic IFU can be downloaded. You need to enter the IFU Code which is printed on the product label to be forwarded to the page where you can download the appropriate IFU. In addition there is a QR code (2D barcode) on each label, which can be scanned by a smartphone and a QR code reader. If you scan this QR Code you'll be directly forwarded to the page with the appropriate IFU.

Before a user first uses a specific medical device of Stemcup a printed version of the specific IFU is provided. In the event of a revision of the IFU every customer will receive it in a printed version.

A printed version of the IFU can by requested at any time. Delivery of a printed version takes 1 to 7 days. Please send your IFU order by email to administration@stemcup.ch or send us a fax on the appropriate fax numbers of Stemcup Switzerland, Germany or Austria.

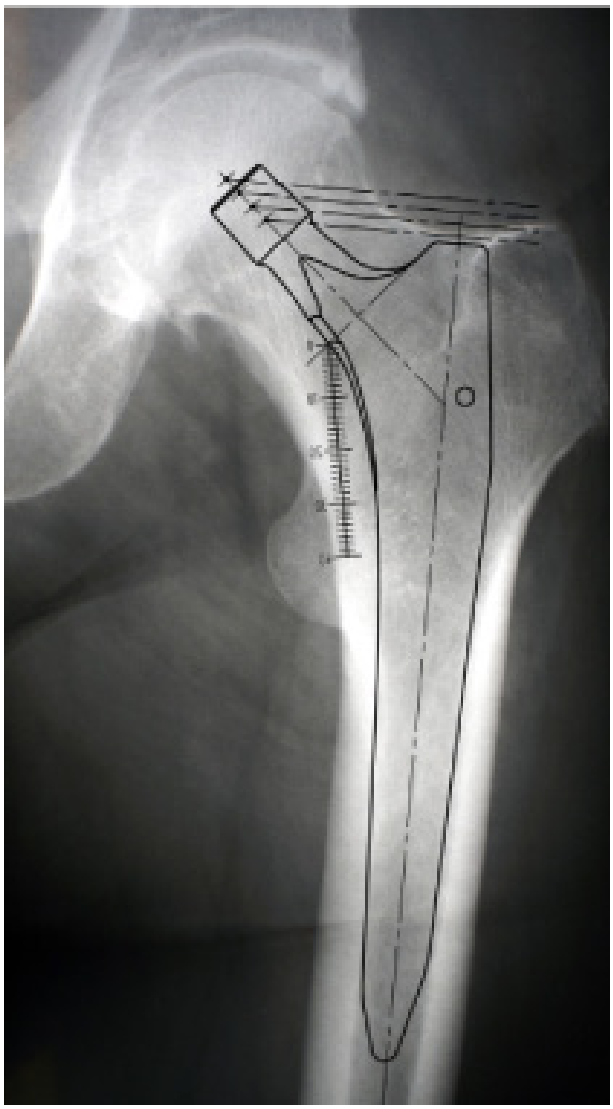


3. Preoperative planning

Preoperative planning is recommended to properly choose the size and orientation of the prosthesis. The offset and neck length achieved with the Stelia Stem are determined by overlaying X-ray templates (enlarged by 15%) on plain radiographs (AP and axial views).

To determine the appropriate entry point for access of instruments to the medullary canal, it is recommended that the surgeon draw the femoral stem axis on the AP radiograph and extend it proximally. This line indicates how far laterally it is necessary to place the box chisel to open up the canal. This entry point is easy to locate during surgery.

It is also helpful to define the position of the Stelia Stem within the canal. This is defined by the distance from the shoulder of the stem to the greater and lesser trochanters, and can serve as an additional intraoperative check of correct stem placement.

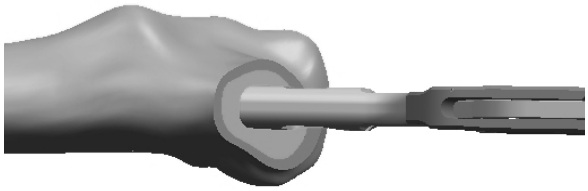


4. Surgical Technique

4.1 Entry into the medullary cavity

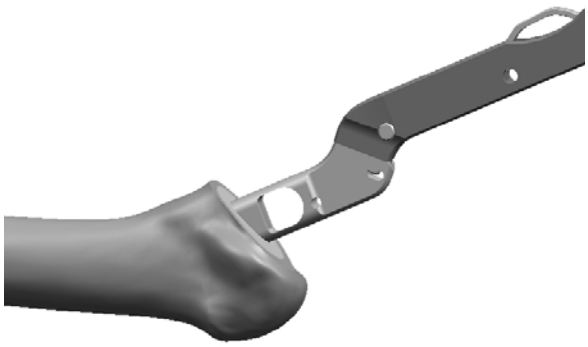
With the lower thigh kept in a horizontal position, the box chisel is placed close to the posterior cortex at the resection level.

The box chisel should be introduced along the femoral axis and a small square block of bone is removed.



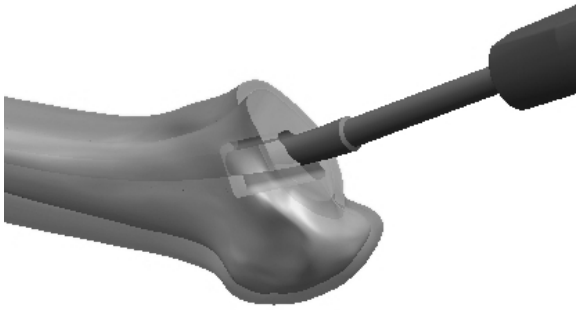
If the box chisel is not used to clear hard bone from the osteotomy site, fracture of the trochanter may occur during rasp insertion.

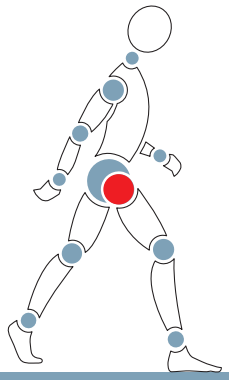
Driving the box chisel below the level of the resected bony surface should also be avoided.



The opening rasp facilitates opening of the diaphyseal medullary cavity.

Further opening of the diaphyseal medullary cavity and probing of the diaphysis with corresponding awl is to be recommended.





4. Surgical Technique

4.2 Optional use of the pilot rasp

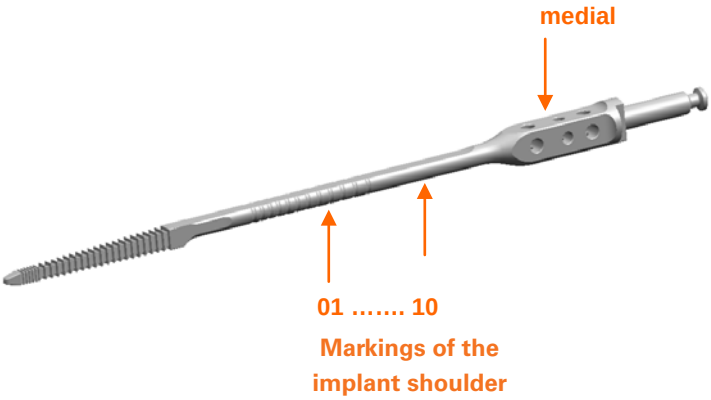
The pilot rasp is used to make neutral alignment of the rasp easier to achieve, thereby preventing varus positioning of the implant. The pilot rasp should be introduced into the canal in the desired degree of anteversion, matching the target rotation of the stem.

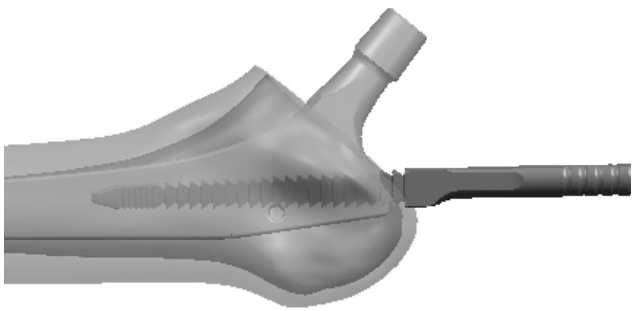
The rasp depth can be controlled using the line markings on the shaft. These markings correspond to the position of the shoulder for each stem size. During insertion of the pilot rasp, care should be taken to restrict its depth of insertion to one or two sizes higher than the shoulder position of the planned implant.

When placing the rasp onto the Impactor attachment or the rasping machine, please ensure that the side marked "MEDIAL" is indeed oriented medially. If the medial and lateral sides are inadvertently reversed, the rasp handle may impinge on the medial aspect of the greater trochanter, preventing neutral alignment.

For correct stem alignment, the rasp must be seated in alignment with the canal axis. Please note that any deviation of the rasp from this axis may lead to varus positioning of the final implant during stem insertion.

After the pilot rasp has been introduced to the desired depth, the detachable rasps are used to create an implantation site of the correct size and alignment for the femoral implant.



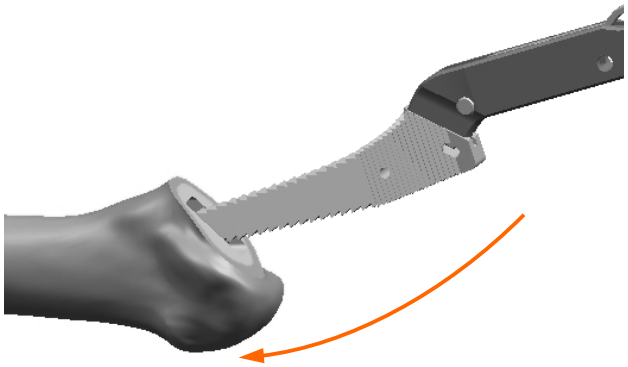


4. Surgical Technique

4.3 Trial rasps

The rasp cuts longitudinal grooves within the femoral cortex. The goal of canal preparation is to make the area of contact between the prosthesis and the cortex as large as possible.

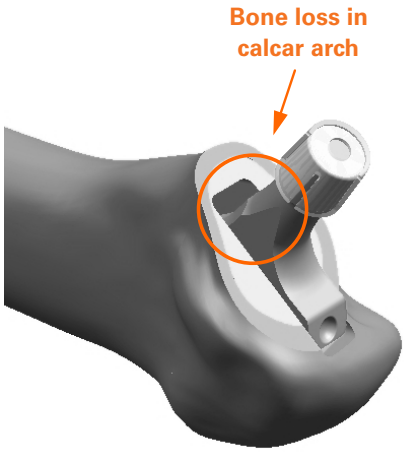
By gradually extending the depth of rasping within the medullary cavity, the area of contact increases, along with the resistance to advancement of the rasp in the canal. Once the rasp is fully engaged within cortical bone, the pitch of the hammer blows increases and traces of pale cortical bone appear within the cutting teeth along the corner edges.



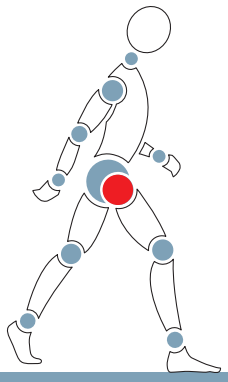
To ensure correct sizing of the stem it is critical that the surgeon establishes the expected size of implant through preoperative planning prior to the surgical procedure.

The initial rasp must be size 01 when preparing the canal for implants of size 4 or smaller. For larger implants (size 5 or greater), the surgeon may start with a rasp of size 1.

At the start of the rasping process, the rasp must not be inserted below the level of the estimated final position of the implant. It is extremely important to understand that the femoral osteotomy has no relationship to the final position.

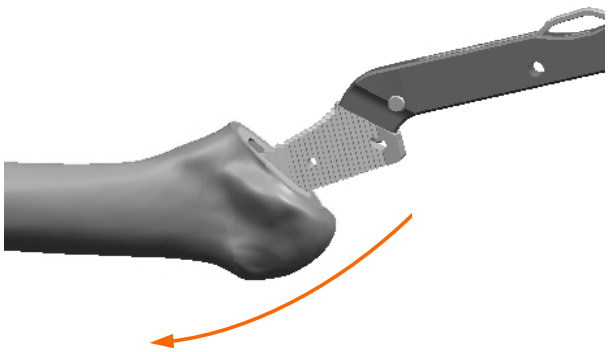


There is a tendency for surgeons to implant the starting smaller size rasps too deeply into the femur. This will result in an excessive enlargement of the implantation site and lead to gaps around the medial aspect of the final implant position.



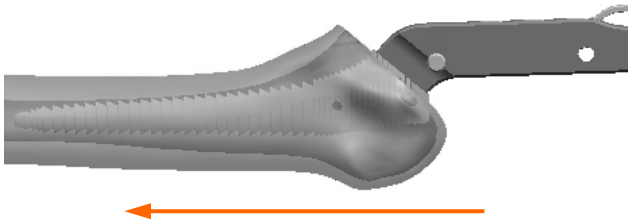
4. Surgical Technique

The subsequent rasp is introduced into the cavity along a slightly arc-shaped path until resistance is felt. The rasp is then driven laterally and distally into the femur with the help of the Impactor attachment or a powerdriven rasping machine. This process is repeated with sequential rasp sizes until the final rasp is seated at an acceptable depth and further up-sizing is not possible. When using the double offset adapters, care should be taken to select the instruments corresponding to the side of the operative extremity.



Because the first rasp determines the position of all subsequent rasps, proper orientation of the first rasp is necessary to ensure correct positioning of the femoral stem.

Attention should be paid to the anteversion and varus/valgus alignment of the rasping machine with respect to the femoral axis.
Insertion of the rasps or the stem in a varus inclination increases the risk of perforation and fracture of the lateral cortex of the femur.



Rasping is carried out using the Impactor attachment or the rasping machine. The weight of these instruments helps to ensure the longitudinal alignment of the rasp within the femur.

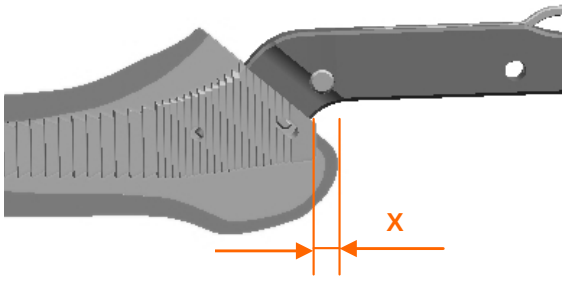
It is important that a lateral force is continuously applied to the rasping machine to ensure that the rasp moves in line with the axis of the canal and does not seat in a varus position.

Unlike the Stelia stem, the Stelia rasp does not enter and exit the canal along the femoral axis, but rather along a curved arc.

4. Surgical Technique

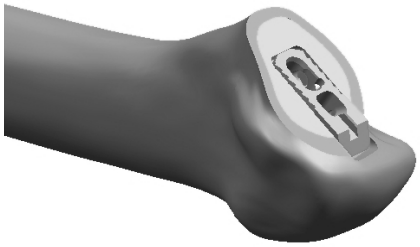
4.4 Trial positioning

The shoulder of the rasp corresponds to the height of the implant, measured at the shoulder of the prosthesis and should correspond to the preoperatively determined distance to the greater trochanter (marked x).



In rare situations, the prosthesis size determined intraoperatively is in disagreement with the size derived from preoperative templating.

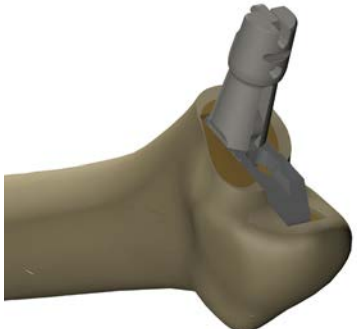
If this difference is two sizes or more, the rasp may not have reached the necessary depth because of incorrect angulation or the presence of an obstacle within the canal.



In such cases, the implanted prosthesis is too small to provide stable long-term fixation.

In these situations, intraoperative fluoroscopy or an intraoperative radiograph should be obtained to evaluate the obstruction.

The offset adapter is removed from the detachable rasp.



The modular neck is attached to the detachable rasp manually.

4. Surgical Technique

The trial ball head can be attached to the modular neck in advance or in situ.

In each case, there is a standard modular neck for the detachable rasps of sizes 01-0, 1-2, 3-4, 5-6, 7-8 and 9-10. The "lateral" modular necks are available to suit the detachable rasps of sizes 1-2, 3-4, 5-6, 7-6 and 9.

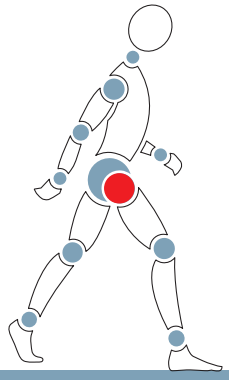
Care should be taken that the modular neck is correctly seated on matching surface of the detachable rasp and engages properly.

The joint is repositioned and leg length, soft-tissue tension, and range of motion are checked by the surgeon. During the initial operations, it is recommended that the surgeon obtain AP and lateral intraoperative radiographs to verify the size and position of the rasp within the femur.

If necessary, the trial ball head and/or the modular neck (standard or lateral) should be changed until a satisfactory result is achieved.

The offset adapter is linked with the detachable rasp. The detachable rasp is removed from the canal using the slap hammer or rasping machine.

Caution!
Removal of the rasp, as with its introduction, must be performed along a curved arc to minimize disturbance of the bone bed and to avoid fractures of any overhanging bone in the trochanteric region.



4. Surgical Technique

4.5 *Implantation of the Stelia stem*

The correct size Stelia stem is introduced manually as deep as possible into the canal, and is then seated with the impactor, using appropriately measured strokes to minimize the risk of fracture of the femur.

Attention:
Pressing the stem in solely by hand is inadequate.

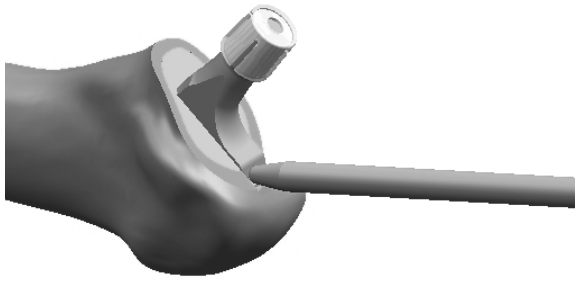
During impact, the protective cover remains positioned on the cone.

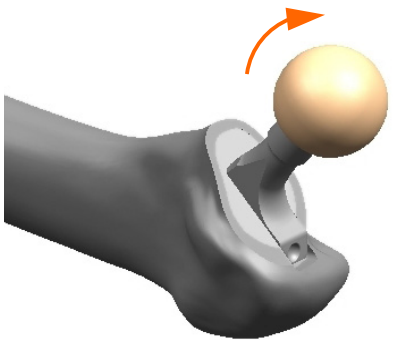
Once the stem is firmly seated, attempts to drive it further down the canal or to adjust its alignment within the femur cannot be performed without fracturing the bone.

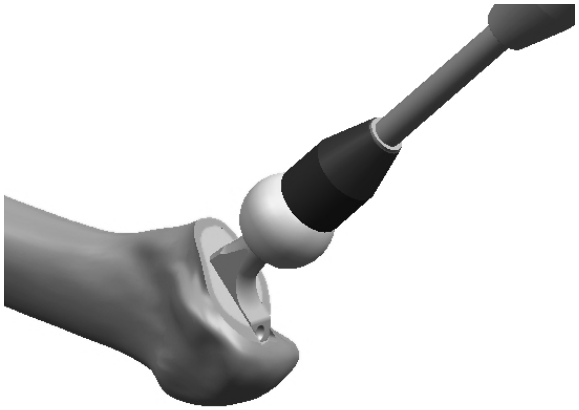
Before repositioning the original ballhead, the taper is carefully cleaned by hand.

The ball head is then attached to the taper with a slight turning motion and permanently fixed with a blow delivered with the Impactor attachment for ball heads.

Attention:
Pressing the prosthetic head onto the taper solely by hand provides inadequate fixation.







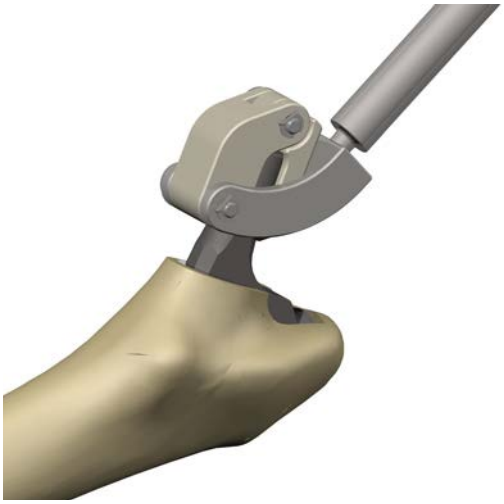
4. Surgical Technique

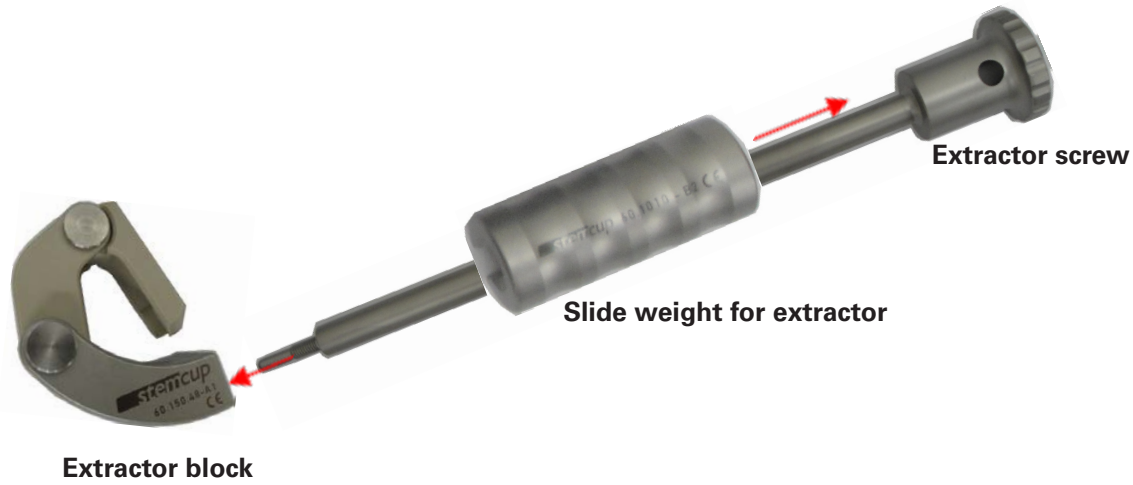
4.6 Postoperative treatment

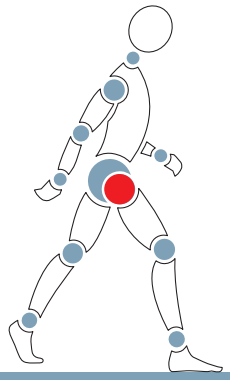
Postoperative rehabilitation should be completed in accordance with each hospital's own practices.

4.7 Explantation of the Stelia stem

The Stelia Stem can be removed using the extractor block with the extraction screw and slide weight for extractor.

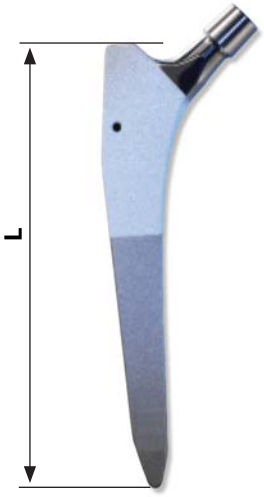






5 Implants ordering overview

5.1 Stelia stem cementless



Stelia Stem standard
Ti/HA coated

Material Ti6Al7Nb / ISO 5832-11 / cone 12/14 / standard CCD 131° / lateralized CCD 127 °

	Stelia standard	Stelia lateralizrd	Stelia standard Ti/HA	Stelia latera-lized Ti/HA basic	Stelia standard basic	Stelia latera-lized basic	length
Sz.	Ref. No.	Ref. No.	Ref. No.	Ref. No.	Ref. No.	Ref. No.	(mm)
01	150.00.15	-	154.00.15	-	152.00.15	-	129
0	150.00.00	-	154.00.00	-	152.00.00	-	132
1	150.00.01	151.00.01	154.00.01	155.00.01	152.00.01	153.00.01	136
2	150.00.02	151.00.02	154.00.02	155.00.02	152.00.02	153.00.02	140
3	150.00.03	151.00.03	154.00.03	155.00.03	152.00.03	153.00.03	144
4	150.00.04	151.00.04	154.00.04	155.00.04	152.00.04	153.00.04	148
5	150.00.05	151.00.05	154.00.05	155.00.05	152.00.05	153.00.05	153
6	150.00.06	151.00.06	154.00.06	155.00.06	152.00.06	153.00.06	157
7	150.00.07	151.00.07	154.00.07	155.00.07	152.00.07	153.00.07	164
8	150.00.08	151.00.08	154.00.08	155.00.08	152.00.08	153.00.08	169
9	150.00.09	151.00.09	154.00.09	155.00.09	152.00.09	153.00.09	175
10	150.00.10	-	154.00.10	-	152.00.10	-	181

Ceramic Ballheads
Ceramic femoral heads Stemox ø28 mm, ø32 mm and BIOLOX®forte ø28 mm, ø32 mm are available in sizes S, M and L.
BIOLOX®delta and BIOLOX®OPTION are available in ø28 mm in sizes S, M, L and in ø32 mm, ø36 mm and ø40 mm in sizes S, M, L and XL.
In case of a possible replacement, a BIOLOX®OPTION femoral head should be used.
Ceramic / ceramic pairs only from the same manufacturer may be used.

Metal Ballheads
Metal femoral heads are available for Stelia stem in diameters ø28 mm, ø32 mm in sizes S, M, L, XL and XXL. Metal femoral heads in diameters ø36 mm and ø40 mm are available in sizes S, M, L and XL.

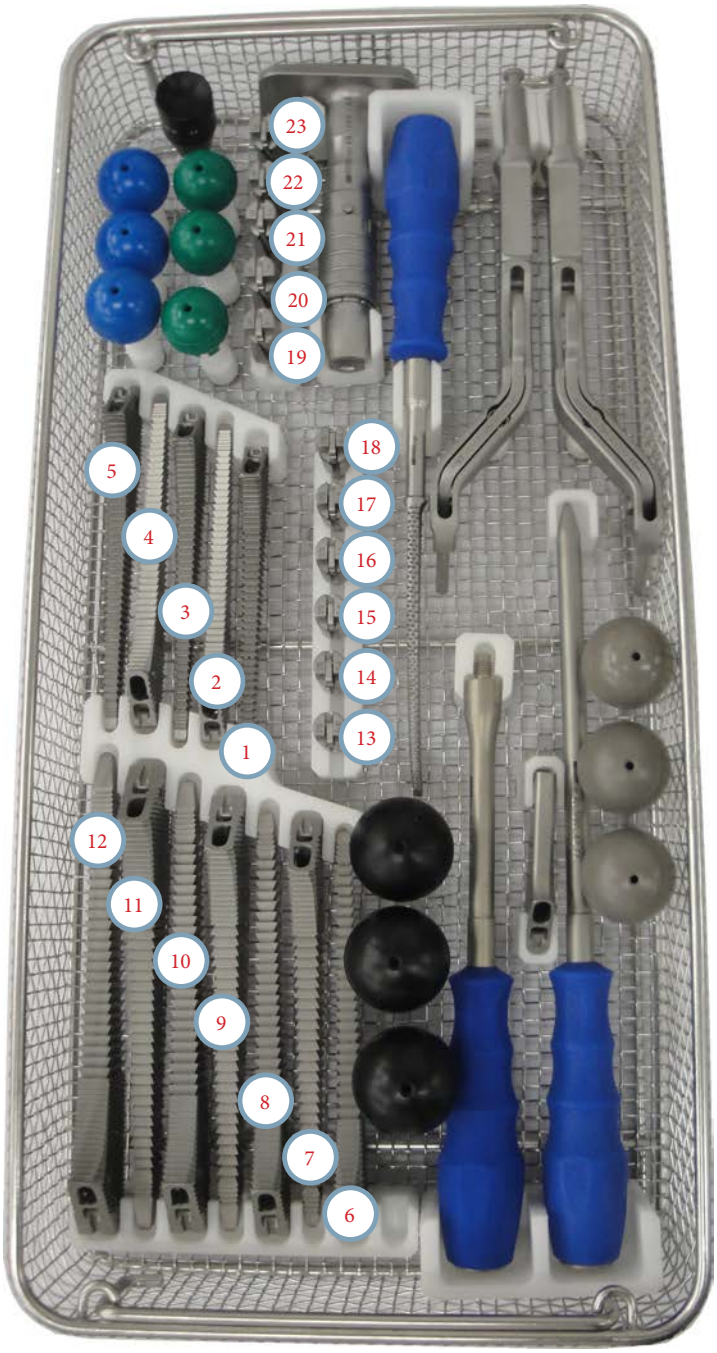
Instruments - Sterility

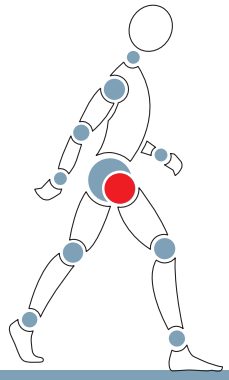
The instruments are not sterile when they are delivered. Before use, they must be reprocessed and sterilized according to Stemcup's Instrument-Leaflet. The instruction leaflet for instruments „Recommendation Care - Cleaning - Maintenance - Sterilization" is available upon request, resp. is inclosed in the instrument set.
Instrument manufacturers and distributors accept no responsibility for sterilization of products by the customer. The applicable legal regulations for the reprocessing of medical devices in your country must be observed. In countries where stricter requirements apply, these must be adhered to.

6. Instruments ordering overview

6.1 Stelia instruments, tray 1/2

Pos.	Ref. Nr.	Description
1	60.150.15	Trialrasp Stelia stem Sz. 01
2	60.150.00	Trialrasp Stelia stem Sz. 0
3	60.150.01	Trialrasp Stelia stem Sz. 1
4	60.150.02	Trialrasp Stelia stem Sz. 2
5	60.150.03	Trialrasp Stelia stem Sz. 3
6	60.150.04	Trialrasp Stelia stem Sz. 4
7	60.150.05	Trialrasp Stelia stem Sz. 5
8	60.150.06	Trialrasp Stelia stem Sz. 6
9	60.150.07	Trialrasp Stelia stem Sz. 7
10	60.150.08	Trialrasp Stelia stem Sz. 8
11	60.150.09	Trialrasp Stelia-Stem Sz. 9
12	60.150.10	Trialrasp Stelia stem Sz. 10
13	60.151.00	Trialtaper STD Sz.01+ Sz.0
14	60.151.01	Trialtaper STD Sz.1 + Sz.2
15	60.151.02	Trialtaper STD Sz.3 + Sz.4
16	60.151.03	Trialtaper STD Sz.5 + Sz.6
17	60.151.04	Trialtaper STD Sz.7 + Sz.8
18	60.151.05	Trialtaper STD Sz.9 + Sz.10
19	60.151.06	Trialtaper LAT Sz.1 + Sz.2
20	60.151.07	Trialtaper LAT Sz.3 + Sz.4
21	60.151.08	Trialtaper LAT Sz.5 + Sz.6
22	60.151.09	Trialtaper LAT Sz. 7 + Sz.8
23	60.151.10	Trialtaper LAT Sz.9





6. Instruments ordering overview

Pos.	Ref. Nr.	Description
24	60.1059	Impactor attachment
25	60.150.31	Opening Rasp
26	60.150.37	Rasphandle left 30 mm Offset
27	60.150.36	Rasphandle reight 30 mm Offset
28	60.1060	Impactor with Siliconhandle
29	60.1061	Impactorhandle
30	60.150.30	Box chisel
31	60.1008	Impactor attachment for ballheads
32	60.28.11	Trial Ballhead ø28 S
33	60.28.12	Trial Ballhead ø28 M
34	60.28.13	Trial Ballhead ø28 L
35	60.32.11	Trial Ballhead ø32 S
36	60.32.12	Trial Ballhead ø32 M
37	60.32.13	Trial Ballhead ø32 L
38	60.36.11	Trial Ballhead ø36 S
39	60.36.12	Trial Ballhead ø36 M
40	60.36.13	Trial Ballhead ø36 L
41	60.40.11	Trial Ballhead ø40 S
42	60.40.12	Trial Ballhead ø40 M
43	60.40.13	Trial Ballhead ø40 L
44	60.150.801.01-90	Tray with Inserts for Ste. Instru.

6. Instruments ordering overview

6.2 Additional instruments to Stelia tray

Ref. Nr.	Description
60.1010	Slide weight for extractor
60.1064	Extractorscrew
60.150.48	Extractor bloc for Stelia stem
60.150.32	Pilotrasp Stelia stem
60.150.34	Rasphandle right 13 mm offset
60.150.35	Rasphandle left 13 mm offset
60.28.14	Trial Ballhead ø28 XL
60.28.15	Trial Ballhead ø28 XXL
60.32.14	Trial Ballhead ø32 XL
60.32.15	Trial Ballhead ø32 XXL
60.36.14	Trial Ballhead ø36 XL
60.40.14	Trial Ballhead ø40 XL
60.1077	Impactor attachment for ballheads ø36
60.1078	Impactor attachment for ballheads ø40

Extractorscrew

Extractor bloc

Slide weight for extractor

Pilotrasp Stelia stem

6.3 Preparation & Accessory

- Cleaning max. 60 min. after use.
- Sterilization is carried out in the assembled state.
- Before use pleas check the Stemcup instrument leaflet „Recommendations Care-Cleaning-Maintenance-Sterilization Instruments“
- Accessories and spare parts can be obtained from the medical adviser responsible for you.

6.4 Repair

Repairs may only be carried out from persons authorized by Stemcup.

Defective instruments sending to:
Stemcup Medical Products AG
Reparaturen& Service
Aargauerstr. 180
CH-8048 Zürich

Note

OVER 30 YEARS OF EXPERIENCE IN MEDICAL TECHNOLOGY

30 YEARS

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We are there when you need us:

Switzerland Headquarters
Stemcup Medical Products AG
Aargauerstrasse 180
CH- 8048 Zürich
Tel. +41 (0)43 311 85 00
Fax. +41 (0)43 311 85 09
info@stemcup.ch
www.stemcup.ch

Germany
Stemcup Medical Products GmbH
Wallbrunnstrasse 24
D-79539 Lörrach
Tel. +49 (0) 7621 162 00 49
Fax. +49 (0) 7621 161 97 78
info@stemcup.de
www.stemcup.de

Austria
Stemcup Medical Products Austria GmbH
Schwindgasse 20/1/4
A-1040 Wien
Tel. +43 (0) 1 890 40 53
Fax. +43 (0) 1 890 40 54
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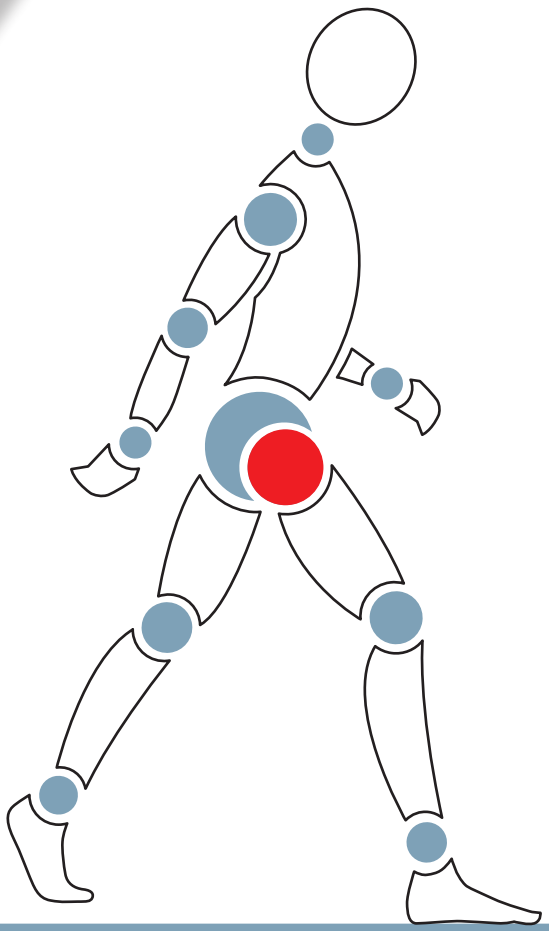

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